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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/489,101	01/21/2000	Ali O. Gure	L0461/7073(JRV)	5361

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EXAMINER	
TON, THAIAN N	

ART UNIT	PAPER NUMBER
1632	15

DATE MAILED: 05/16/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/489,101	Applicant(s) GURE ET AL.	
	Examiner Thaian N. Ton	Art Unit 1632	

-- The MAILING DATE of this communication appears on th cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 February 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,7,16,50,52,63,65,70-72,78-80,85,88,98,102,109,115 and 117-127* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *12* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Continuation of Disposition of Claims: Claims pending in the application are 1,2,7,16,50,52,63,65,70-72,78-80,85,88,98,102,109,115 and 117-127.

DETAILED ACTION

Note that the Examiner of record has changed. The Examiner of record is now Thaian N. Ton of Art Unit 1632.

Applicants' Amendment, filed 2/20/02, has been entered. Claim 1 has been amended.

Claims 1, 2, 7, 16, 50, 52, 63, 65, 70-72, 78-80, 85, 88, 98, 102, 109, 115 and 117-127 are pending.

Claims 1, 2, 117-127 are under current examination.

Any rejection made of record in the prior Office action, mailed 6/21/01, Paper No. 11, and not made of record in the instant Office action, has been withdrawn in view of Applicants amendments to the claims.

Information Disclosure Statement

Applicants' Information Disclosure Statement, filed 12/7/01 has been considered.

Response to Arguments

The rejection of claims 1, 2, 117-120 and 127 under 35 USC 112, 1st paragraph, for written description is maintained. The rejection of claims 121-126 for written description has been withdrawn.

The rejection of claims 1, 2, and 117-127, under 35 USC 112, 1st paragraph, for enablement, has been withdrawn.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code. Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01. See p. 62, lines 25, 27 and 28.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The prior rejection of claims 1, 2 and 117-120 and 127 under 35 U.S.C. 112, first paragraph, is maintained, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claimed invention is directed to methods of diagnosing a disorder characterized by the expression of a human cancer-associated antigen precursor coded for by a nucleic acid molecule, comprising contacting a biological sample

isolated from a subject with an agent that binds under stringent hybridization conditions to the nucleic acid molecule, an expression product thereof, or a fragment of an expression product thereof complexed with an HLA molecule, wherein the nucleic acid molecule is a NA Group I nucleic acid molecule, and determining the interaction between the agent and the nucleic acid molecule or the expression product as a determination of the disorder.

Vas-Cath Inc. v. Mahurkar, 19USPQ2d 1111 (Fed. Cir. 1991), clearly states that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention.* The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed.*" Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1117. The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed. Vas-Cath Inc. v. Mahurkar, 19USPQ2d at 1116.

The specification teaches that NA Group 1 consists of (a) nucleic acid sequences consisting of SEQ ID Nos: 3-17, (b) deletions, additions, and substitutions which code for a respective cancer associated antigen precursors, (c) nucleic acid molecules that differ from nucleic acid molecules of (a) or (b) due to degeneracy of the genetic code, and (d) complements of (a), (b) and (c) [see pp. 15-16, bridging paragraph]. However, the specification fails to describe deletions, additions or substitutions, different nucleic acids, complements, or fragments thereof of the

nucleic acids in NA group 1, as encompassed by the claims, with particularity to indicate that Applicants had possession of the claimed invention.

Applicants present the controlling case law for adequate written description of a nucleic acid molecule [*University of California v. Eli Lilly and Co.*]. Particularly, that the Court ruled that a proper written description, "of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus." [See pp. 2-3 of the Response]. Applicants argue that there is adequate written description in the instant application, as Applicants have provided both structural and physical properties of the claimed nucleic acid molecules [see p. 3, 3rd paragraph of the Response]. Applicants state that the NA group 1 nucleic acid molecule fragments are set forth in detail in the specification on p. 19, lines 23-24, stating that a unique fragment is one that is a 'signature' of the larger nucleic acid, and that the larger nucleic acid is selected from the group consisting of SOX2, SOX 1, ZIC2, SOX3, and SOX21. However, it is noted that although dependent claims [see claim 121] limit the claimed invention to the above-described sequences, the broad claim recites nucleic acid molecules from NA Group 1 nucleic acid molecule, which is defined in the specification [see p. 15-16, bridging paragraph and *supra*]. As such, although Applicants have adequately described the nucleic acid sequences of SOX2, SOX 1,

ZIC2, SOX3, and SOX21, Applicants have not adequately described a representative number of species of biochemical or molecular structures of encompassed by the nucleic acid molecules in NA Group 1, or fragments thereof.

Note that the claimed invention as a whole is not adequately described if the claims require essential or critical elements which are not adequately described in the specification and which are not conventional in the art **as of Applicants effective filing date**. Possession may be shown by actual reduction to practice, clear depiction of the invention in a detailed drawing, or by describing the invention with sufficient relevant identifying characteristics (as it relates to the claimed invention as a whole) such that a person skilled in the art would recognize that the inventor had possession of the claimed invention.

In the instant case, the claimed embodiment of NA Group 1 nucleic acid molecules, or fragments thereof, lacks a written description. The specification fails to describe, for example, what deletions, additions and/or substitutions would code for a respective cancer associated antigen precursor, or fragments thereof, which would fall into this genus when used as claimed. The skilled artisan cannot envision the detailed structure and/or sequence of the genus of the claimed NA Group I nucleic acid molecules and fragments thereof, therefore conception is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of

isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016 (Fed. Cir. 1991).

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes*, claims directed to mammalian FGF's were found to be unpatentable due to lack of written description for that broad class. The specification provided only the bovine sequence.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 2 and 117-127 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: comparison between the amount or degree of interaction between an agent and nucleic acid molecule from a biological sample from a patient suffering from cancer and the interaction in a biological sample of normal tissue.

The specification teaches that in normal tissues, ZC12 is only expressed in the brain, testis and tumors [see Example 3], and that SOX1, SOX3 and SOX21

expression is not detected in normal adult tissues, and that SOX2 expression is detected in various normal tissues [see Example 4]. In order to diagnose a disorder by utilizing the nucleic acid molecules in the NA Group 1, one would have to be able to differentiate between normal tissues that express the nucleic acid molecules encompassed by NA Group 1, and cancerous tissues that express the nucleic acid molecules encompassed by NA Group 1, and as such, comparison steps such as comparing levels of hybridization, would be essential to the claimed invention. As such, measuring a mere "interaction" as recited in claim 1, would not be sufficient to determine a disorder. Furthermore, as evidenced by the specification, not all of the genes encoded by the nucleic acid molecules in NA Group 1 are expressed equivalently in normal tissues. As such, Applicants should provide, with particularity, particular ways of measuring the interaction between the agent and different nucleic acid molecules encompassed by NA Group 1. Claims 2, 117-127 depend from claim 1.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Thaian N. Ton whose telephone number is (703) 305-1019. The examiner can normally be reached on Monday through Friday from 8:00 to 5:00 (Eastern Standard Time), with alternating Fridays off. Should the examiner be unavailable, inquiries should be directed to Deborah Reynolds, Supervisory Primary Examiner of Art Unit 1632, at (703) 305-4051. Any administrative or procedural questions should be directed to Patsy Zimmerman, Patent Analyst, at (703) 305-2758. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 308-8724.

Deborah Crouch

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